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K010250

510(k) Summary of Safety and Effectiveness

The following 510(k) Summary of Safety and Effectiveness has been prepared pursuant to requirements for 510(k) summaries specified in 21 CFR § 807.92(a).

807.92(a)(1) - Submitter Details:

Submitter name:	Adi Ickowicz - Corporate Director of IP, Regulatory Affairs and Quality
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Contact Person:	Adi Ickowicz - Corporate Director of IP, Regulatory Affairs and Quality
Date:	February 26, 2001

807.92(a)(2) - Device Details:

Trade Name and Common Name:	PoleStar N-10 Software Ver. 1.2.0 - Magnetic Resonance Diagnostic Device
Classification:	21 CRF 892.1000 Magnetic Resonance Diagnostic Device.
Class:	II MRDD were reclassified by FDA from Class III to Class II effective July 28, 1998.
Product Code:	LNH - Magnetic Resonance Imaging System
Performance Standards:	No applicable performance standards have been issued under section 514 of the Food and Drug and Cosmetic Act.

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807.92(a)(3) – Predicate Devices:

The PoleStar N-10 with its modified software is comparable to the following devices listed in the following table:

Medical Device Name	Applicant Name	510(k) Number	Classification
PoleStar N-10	Odin Medical Thechnologies Ltd.	K002242	Class II device
VectorVision	BrainLAB Navigation System	K983831	Class II device
Voyager	Marconi Medical System Inc.	K000310	Class II device

Additional Substantial Equivalence Information is provided in the attached Substantial Equivalence Comparison Table.

807.92(a)(4) – Device Description:

The PoleStar N-10's Software Ver. 1.2.0 image guidance feature enables the surgeon to mark clinically relevant structures or sites whose anatomical nature is visually ambiguous. A marker corresponding to the location is displayed on the system screen, providing the exact anatomic orientation. The marker can be displayed on axial, coronal, sagittal or oblique slices. Prior to the operation, images are acquired with the Polestar N-10 (K002242) to plan the optimal trajectory of approach to the lesion. The surgeon uses these images, to evaluate possible paths to the lesion, thus allowing a safe and controlled approach to the lesion. During the procedure the planned trajectory can be displayed on newly acquired images, allowing the surgeon to both monitor progress and detect changes caused by changing intraoperative conditions. The Polestar N-10's Software Ver. 1.2.0 image guidance feature is based on images acquired intraoperatively, thus eliminating problems caused by brain shift during Neurosurgery.To allow Image guidance an infrared (IR) camera is required. This camera emits infrared energy that is reflected by passive reflecting spheres mounted on the optical wand, PRF and DRF. The Infrared (IR) camera detects the reflected infrared light from different angles and the software uses these data to calculate the spatial position of each passive reflecting sphere, and thereby the position of the tracked device.

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807.92(a)(5) – Device Intended Use:

The intended use of the PoleStar N-10 software version 1.2.0 is to provide surgeons with the image guidance feature which allows orientation and reference information during intraoperative procedures. This gives the surgeons the ability to plan the surgical approach to the treatment location of the patient.

807.92(a)(6) – Substantial Equivalence Comparison Table:

The submitted software was embaded within the PoleStar N-10 FDA cleared software. This Software Ver. 1.2.0 has the image guidance functioins activated and also includes the additional hardware accessories to allow the localization process.

Model / Parameter	Candidate Device	Predicate Devices	
	PoleStar N-10 Software Ver. 1.2.0	VectorVision	Voyager
Tools and Accessories	Probe, Dynamic tracker and dynamic reference frame	Probe with various length tips, drill guide, tracking devices, and phantoms.	Probe with various length tips, drill guide, tracking devices, and phantoms.
Tool Sterilization	Steam sterilization	Steam sterilization	Steam sterilization
Type of detector/Position Sensor Assembly (PSA)	NDI Polaris Camera	NDI Polaris Camera	NDI Polaris Camera
Registration Technique	Permanent fiducials fixed on the magnet poles	Scanned fiducials and anatomical fiducials	Scanned fiducials and anatomical fiducials
Active Digitizer Volume	1x1x1 meter	1x1x1 meter	1x1x1 meter
Software Platform	Windows NT	Windows NT	Unix

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Model / Parameter	Candidate Device	Predicate Devices	
	PoleStar N-10 Software Ver. 1.2.0	VectorVision	Voyager
Graphical User Interface	Uses a graphical interface to facilitate interaction with user	Uses a graphical interface to facilitate interaction with user	Uses a graphical interface to facilitate interaction with user
Image Manipulation Capabilities	Reformated views of scanned data for orientation and navigation and navigation on original images. Graphical representation of tool location and orientation in space	Reformated views of scanned data for orientation and navigation. 3D rendering	Reformated views of scanned data for orientation and navigation. 3D rendering

Performance Data:

Substantial equivalence was based on performance data. Clinical data was not required. The data regarding localization accuracy is provided in attachment 3 of the 510(k) submission.

Conclusions:

The PoleStar N-10 Software Ver. 1.2.0 is of similar technology and has the same intended use as its predicate devices. Furthermore and based on the performance data obtained, it does not raised any additional safety or efficacy concerns. Therefore the PoleStar N-10 Software Ver. 1.2.0 is substantially equivalent to its predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Odin Medical Technologies, Ltd.
% Cynthia J.M. Nolte, Ph.D., RAC
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

Re: K010850
Trade/Device Name: PoleStar N-10 (MRI Guide)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH
Dated: September 28, 2001
Received: October 1, 2001

Dear Dr. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K010850

Device Name: **PoleStar N-10 Software Version 1.2.0 - Magnetic Resonance Diagnostic Device**

Indication For Use:

The intended use of the PoleStar N-10 Software Version 1.2.0 is to provide surgeons with the image guidance feature which allows orientation and reference information during intraoperative procedures. This gives the surgeons the ability to plan the surgical approach to the treatment location of the patient.

(PLEASE DO NOT WRITE BELOW THE LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Lyerson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K010850